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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC.,

Plaintiffs and Counterclaim-Defendants,

v.

HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD.,

Defendants and Counterclaim-Plaintiffs.

Oral Argument Requested

Civil Action No. 3:11-CV-00760-JAP-TJB

Judge Joel A. Pisano
Magistrate Judge Tonianne J. Bongiovanni

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT NO. 3: INVALIDITY OF U.S. PATENT NO. 5,714,504 - CLAIMS 1-2, 4, 6 AND 7 BASED ON "SOLID STATE"

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I. INTRODUCTION

AstraZeneca's[1] U.S. Patent No. 5,714,504 in suit (the "'504 Patent"; Parezo Decl. Exh. B)[2] describes and claims pharmaceutical formulations comprising the pure solid state alkaline salts of esomeprazole[3] and methods for inhibiting gastric acid production and treating gastrointestinal inflammatory disease. The claimed inventions are based on the discovery that esomeprazole has certain improved properties, and provides certain biological benefits, as compared to omeprazole. For example, the inventors discovered that esomeprazole produces improved pharmacokinetic and metabolic properties, which will give an improved therapeutic profile, such as a lower degree of interindividual variation. (Parezo Decl. Exh. B, col.1 ll. 50–53.)

Hanmi[4] has applied for permission from the U.S. Food and Drug Administration to sell a generic version of Nexium® that uses esomeprazole strontium, prior to the expiration of the '504 Patent. In its Motion 3, Hanmi contends that the '504 Patent does not meet the written description, enablement, and definiteness requirements of Section 112 of the Patent Code. Each argument advanced by Hanmi is inconsistent with its expressed willingness to be bound by the Court's prior ruling that "solid state" had a clear meaning to skilled artisans.

In a May 18, 2010 opinion in another action involving the '504 Patent, *AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd.*, Civ. A. No. 05-5553 (JAP), 2010 WL 1981790 (D.N.J. May 18,

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[1] "AstraZeneca" refers collectively to plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc.

[2] Submitted herewith are the Declarations of Jessica L. Parezo ("Parezo Decl."), Dr. Stephen G. Davies ("Davies Decl.") and Hon. Lawrence J. Goffney, Jr. ("Goffney Decl.").

[3] Esomeprazole is also known as the (–)-enantiomer of omeprazole, (–)-omeprazole, (S)-omeprazole, and the S-enantiomer of omeprazole.

[4] "Hanmi" refers collectively to defendants Hanmi, Inc.; Hanmi Pharmaceutical Co., Ltd.; Hanmi Fine Chemical Co., Ltd.; and Hanmi Holdings Co., Ltd.

2010) (Pisano, J.) (henceforth "*Dr. Reddy's*"), this Court held that the term "solid state" in the '504 Patent had a plain and clear meaning to persons of ordinary skill in the art. *Id.* at *9. Hanmi has agreed to be bound by this decision. In a letter to the Court, Hanmi states that the instant summary judgment motion "seeks a judgment of invalidity of the asserted claims of the '504 Patent based on their inclusion of the term 'solid state,' which was previously construed by the Court." (Defs.' Ltr. to Court of Oct. 19, 2011, n.1, D.I. 121.) Hanmi has confirmed its agreement to be bound by the Court's decision by omitting "solid state" from the list of terms requiring construction in the claim construction proceedings of this case. (*See* Joint Claim Constr. & Preh'g Stmt. of Sept. 14, 2011, D.I. 92.)

Hanmi's motion should be denied. Hanmi's motion should be precluded by, at least, its agreement to be bound by this Court's prior decision. Contrary to Hanmi's argument, this Court did not find that the term "solid state" excludes material in a "solid form," as Hanmi now says is required. This Court simply determined that for "solid state": 1) its ordinary and customary meaning would be clear to one skilled in the art, and 2) the plain meaning of the term as understood by someone of ordinary skill shall apply. Not only is Hanmi's position inconsistent with the Court's prior Order, but Professor Stephen G. Davies, an expert in organic chemistry, confirms that a person of ordinary skill in the art would have understood "solid state" to mean solid material, whether crystalline or amorphous. (Davies Decl. ¶ 83). For all these reasons, Hanmi's Motion 3 that alleges that claims 1, 2, 4, 6 and 7 of the '504 Patent are indefinite must fail. Hanmi's arguments for invalidity based on lack of written description and enablement also rely on its failed allegation of alleged indefiniteness of "solid state." These arguments, too must fail, and summary judgment should be denied with prejudice.

AstraZeneca respectfully requests that the Court confirm its ruling in *Dr. Reddy's* that the ordinary and customary meaning of "solid state" would be clear to a skilled person, and rule, now, that the plain meaning of "solid state" is "solid material in any form." Because resolution of Motion 3 depends on these claim construction issues, AstraZeneca proposes that the Court schedule resolution of Motion 3 as part of the ongoing *Markman* proceedings.

Finally, disputed issues of material fact also preclude summary judgment. Hanmi is not only moving for summary judgment on an inherently factual issue, but is doing so before any discovery—fact or expert—has taken place. Hanmi relies heavily on the declaration of an expert whom Plaintiffs have had no opportunity to depose. Plaintiffs expect that a deposition would reveal further disputed issues of material fact. Plaintiffs have provided a declaration from Professor Davies that confirms what the Court already knows: that the meaning of "sold state" is plain and clear to persons of skill in the art.

II. FACTUAL BACKGROUND

Omeprazole is a racemic mixture of its two single enantiomers, the (+)-enantiomer and the (–)-enantiomer. The (–)-enantiomer of omeprazole is also known as "esomeprazole." The inhibition of gastric acid secretion is desirable in the treatment of gastric acid-related diseases and gastrointestinal inflammatory diseases in mammals and man, such as gastric ulcer, duodenal ulcer, reflux esophagitis and gastritis. (Parezo Decl. Exh. B, col.2 ll.17–23.)

The '504 patent[5] relates to pure alkaline salts of (–)-omeprazole (Parezo Decl. Exh. B, col.2 l.42– col.3 l.35; col.5 ll.12–20) and pharmaceutical formulations and methods for treating gastric acid-related conditions. The inventors found that the newly discovered alkaline salts of

[5] All discussion herein of the '504 Patent disclosure applies equally to the disclosure of the original patent application from which the '504 Patent directly issued.

(–)-omeprazole provided advantages of purity and stability, which result in improved pharmacokinetic properties. (*Id.* col.13 ll.31–48.) The '504 Patent further relates to the inhibition of gastric acid secretion and treatment of gastric acid-related conditions and gastrointestinal diseases. (*Id.* col.2 ll.16–30.)

This Court previously has held, in an order that Hanmi agreed to be bound by, that the ordinary and customary meaning of "solid state" is clear and, therefore, that its plain meaning applies in the claims of the '504 Patent. *Dr. Reddy's*, at *9. In *Dr. Reddy's*, AstraZeneca had proposed that "solid state" should be construed as "a solid form rather than liquid, such as, a syrup or oil." *Id.* The defendant, Dr. Reddy's Laboratories, had proposed that no construction of "solid state" was necessary or, in the alternative, that it should be construed as "solid form." *Id.* The Court stated:

> With respect to its proposed construction, Astra provides no justification for the language that distinguishes a "solid form" from a "liquid, such as, a syrup or oil." Moreover, the Court agrees with DRL that no construction of this term is necessary *finds that its ordinary and customary meaning would be clear to one skilled in the art*. Therefore, *the plain meaning of the term as understood by someone of ordinary skill shall apply*.

Id. (emphases added).

"Solid state" does, in fact, have a plain and ordinary meaning to a person of ordinary skill in the art. (AZ SOF ¶¶ 106; 129.) Professor Davies, an expert in organic chemistry, confirms that one of ordinary skill in the art would have understood "solid state" to mean solid material in any form. (Davies Decl. ¶ 83; AZ SOF ¶ 109.) Such solid material would have included crystalline solids and amorphous solids. (Davies Decl. ¶ 83; AZ SOF ¶ 109.) A person of ordinary skill in the art would also have understood that crystalline solids and amorphous solids could be used to form solid pharmaceutical formulations, including powder and tablets. (Davies Decl. ¶ 83; AZ SOF ¶ 110.)

A person of ordinary skill in the art in 1993 would have understood, based on the '504 Patent specification, that the clamed solid state salts were described in the specification and that the inventors had possession of the claimed solid state salts. (Davies Decl. ¶ 95; AZ SOF ¶¶ 130–132.) In addition, a person of ordinary skill in the art would have understood how to make and use the claimed solid state salts, based on the '504 Patent specification. (Davies Decl. ¶ 135; AZ SOF ¶¶ 133–152.) Moreover, and consistent with this Court's determination in *Dr. Reddy's*, a person of ordinary skill in the art would have found the claimed solid state salts to have a plain and ordinary meaning in the art and clear scope. (Davies Decl. ¶ 93; AZ SOF ¶¶ 106; 108–110; 129.)

III. LEGAL STANDARDS

A. Definiteness

A claim can be found indefinite only if the challenger proves that it is "insolubly ambiguous." *Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1346 (Fed. Cir. 2004). Before a claim can be found to be indefinite, an effort must be made to construe it. *See, e.g.*, *Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1368 (Fed. Cir. 2006) ("An analysis of claim indefiniteness under § 112 ¶ 2 is inextricably intertwined with claim construction.") (internal quotation marks omitted); *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 780 (Fed. Cir. 2002) ("[Determining indefiniteness] requires a construction of the claims according to the familiar canons of claim construction. Only after a thorough attempt to understand the meaning of a claim has failed to resolve material ambiguities can one conclude that the claim is invalid for indefiniteness.").

B. Written Description

Lack of an adequate written description must be established by the challenger by clear and convincing evidence. *Hynix Semicond'r Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011) (citing *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009)).

The written description requirement is satisfied if "the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written description requirement "does not demand any particular form of disclosure," and it is well established that the specification need not "recite the claimed invention *in haec verba*." *Id.* at 1352. Inherent disclosure is sufficient to provide written description support for the claimed invention. *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1313–14 (Fed. Cir. 2010).

"The test [for written description] requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. . . . This inquiry, as we have long held, is a question of fact." *Ariad*, 598 F.3d at 1351; *see, e.g.*, *Union Oil Co. Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 996 (Fed. Cir. 2000) ("In written description cases, the primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.") (internal quotation marks omitted).

Because written description is a question of fact, courts have recognized that it typically cannot be resolved on summary judgment. *See, e.g.*, *In re Gabapentin Patent Litig.*, 395 F. Supp. 2d 175, 180 (D.N.J. 2005) (denying summary judgment of invalidity based on written description and noting that "[t]he relevant inquiry is factual and focuses on whether one skilled in the art would understand the supporting language in the specification to describe the same

inventive concept found in the claims."). The District Court of New Jersey has recognized that conflicting expert affidavits in particular are sufficient basis for denying summary judgment on written description: "*That expert affidavits conflict* concerning the written description requirement has been held sufficient to preclude summary judgment." *Id.* (emphasis added).

C. Enablement

A claim is enabled if the patent specification "teach[es] those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Martek Biosci. Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009) (internal quotation marks omitted). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many *factual* considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (emphasis added). In other words, "[t]hat some experimentation is necessary does not preclude enablement." *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). Rather, a "considerable amount of experimentation is permissible, if it is merely routine." *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

In *Wands*, 858 F.2d at 737, the Federal Circuit identified the eight distinct factual issues that may be pertinent to whether the enablement requirement is satisfied. However, "it is not necessary that a court review all the *Wands* factors to find a disclosure enabling. They are illustrative, not mandatory. What is relevant depends on the facts." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

In addition, it is well established that to satisfy the enablement requirement, "[t]he specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation.'" *Amgen*

Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003); *see, e.g.*, *In re Gaubert*, 524 F.2d 1222, 1226 (CCPA 1975) ("Enablement is the criterion, and every detail need not be set forth in the written specification if the skill in the art is such that the disclosure enables one to make the invention.") (internal quotation marks omitted).

D. Summary Judgment

Summary judgment may not be granted unless the moving party demonstrates that there is no genuine dispute of material fact and that the undisputed facts establish the movant's entitlement to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). Courts may grant summary judgment only "when no reasonable jury could return a verdict for the nonmoving party." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998) (internal quotation marks omitted).

In considering a motion for summary judgment, the Court must "view the evidence in a light most favorable to the party opposing the motion with doubts resolved in favor of the opponent." *Ethicon*, 149 F.3d at 1315. Evidence in support of summary judgment "is viewed through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1339–40 (Fed. Cir. 2010). Because patents carry a strong presumption of validity, *see* 35 U.S.C. § 282, Hanmi must prove the disputed facts underlying an invalidity contention by clear and convincing evidence, a burden which is "constant and never changes." *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2243 (2011) (internal quotation marks omitted).

Summary judgment should be denied when a dispute of material fact exists between the parties regarding the adequacy of the disclosure in a patent application to which a later-filed application claims priority. *See Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1359 (Fed. Cir. 2010) (affirming the District Court's denial of summary judgment because

irreconcilable testimony regarding the adequacy of the disclosure in a provisional patent application created a dispute of material fact).

IV. HANMI'S MOTION 3 OF INVALIDITY SHOULD BE DENIED

Hanmi's Motion 3 should be denied for several reasons. First, Motion 3 for a summary judgment of indefiniteness is foreclosed by its agreement to be bound by the Court's prior ruling that the term "solid state" has a plain and ordinary meaning that is clear to persons of ordinary skill in the art. Plainly, a claim term whose meaning is "clear" cannot render a claim indefinite.

Hanmi represented to the Court that it is not challenging the Court's prior construction of the term "solid state." (Defs.' Ltr. to Court of Oct. 19, 2011, n.1, D.I. 121; Joint Claim Constr. & Preh'g Stmt. of Sept. 14, 2011, D.I. 92.) If Hanmi disagreed with the Court's decision that the term would be clear to a person of ordinary skill in the art, Hanmi should have raised the issue during the *Markman* proceedings in this case. It did not do so. Hanmi should not be allowed to circumvent the Court's *Markman* proceedings through summary judgment. Accordingly, Hanmi's motion for a summary judgment of indefiniteness should be denied.

A. The meaning of "solid state" would be clear to one skilled in the art

The Court has already determined and Hanmi has already agreed that the meaning of "solid state" would be clear to one of ordinary skill in the art. *Dr. Reddy's*, at *9. Yet Hanmi now asserts that a that the Court held to have a plain and ordinary meaning and is clear to persons of ordinary skill in the art somehow has "fatal ambiguity" that renders it indefinite (Defs.' Br. Summ. J. 23.) Hanmi should be bound by its representations in this case. Hanmi's assertion cannot be squared with this Court's conclusion.

B. "Solid state" means "solid material" to a person of skill in the art

The term "solid state" had a clear meaning to persons of ordinary skill in the art. Professor Davies explains that a one of ordinary skill in the art would have understood, based on the '504 Patent disclosure, that the meaning of "solid state" was plain and clear. (Davies Decl. ¶¶ 78–93; AZ SOF ¶ 106.) The plain meaning of "solid state" is solid material in any form. (Davies Decl. ¶ 83; AZ SOF ¶ 109.) Solid material would have included at least crystalline solids and amorphous solids, as well as solid pharmaceutical formations such as powders and tablets. (Davies Decl. ¶ 83; AZ SOF ¶¶ 109–110.) This understanding of the scope of the term "solid state alkaline salts of (–)-omeprazole" by one of ordinary skill establishes that the '504 Patent satisfies the definiteness requirement of Section 112.

AstraZeneca respectfully requests that the Court adopt "solid material" as the meaning of "solid state," an issue of claim construction, as part of the ongoing *Markman* proceedings.

C. "Pure solid state alkaline salts" are described in the '504 Patent

Hanmi falls far short of carrying its burden of establishing, based on undisputed facts, that claims 1, 2, 4, 6 and 7 of the '504 Patent fail to satisfy the written description requirement of Section 112. The claims of the '504 Patent are presumed to be supported by an adequate written description. Hanmi has failed to establish by clear and convincing evidence that the patent does not meet this requirement. *Hynix*, 645 F.3d at 1351 (citing *ICU Med.*, 558 F.3d at 1376).

Hanmi's written description argument rests on two fundamental errors. First, Hanmi mistakenly asserts that a person of skill in the art would have found the term "solid state" unclear. (Defs.' Br. Summ. J. 10.) Second, Hanmi's argument disregards that the written description requirement "does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*." *Ariad*, 598 F.3d at 1352 (internal

citation omitted). Although Hanmi makes much of the absence of the phrase "solid state" in the specification, it is well established that the specification does not need to use the exact same terms as used in the claims to satisfy the written description requirement. *See Spine Solutions*, 620 F.3d at 1313–14 (granting summary judgment of adequate written description upon determining that "[t]he fact that the specification never mentions the word . . . is not sufficient to create a genuine dispute of material fact"); *see also Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1154 (Fed. Cir. 2004) (holding that terms need not be used *in haec verba*). On the contrary, "[t]he fact . . . that the exact words . . . in question . . . are not in the specification is not important" to the written description inquiry. *In re Wright*, 866 F.2d 422, 425 (Fed. Cir. 1989).

Indeed, with respect to newly-added claim language involving forms of material, the Federal Circuit has confirmed that the patent application need not expressly include details on such forms of material. In *All Dental Prodx*, 309 F.3d at 779, the Federal Circuit considered the written description support for the claimed phrase "original unidentified mass" of material for making dental impressions. The application as originally filed did not contain this phrase, nor did it mention the shape or form of the mass anywhere in the patent specification. *Id.* However, the Federal Circuit held that the claimed phrase satisfied the written description requirement because "the failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented." *Id.* The Federal Circuit reversed the District Court's grant of summary judgment of invalidity. *Id.*

The holding of *All Dental Prodx* is squarely applicable here. The '504 Patent discloses and teaches how to make alkaline salts of (–)-omeprazole that are in crystalline form, amorphous form, powders or tablets—all forms that a person of ordinary skill would recognize as solid state.

Professor Davies explains that a person of ordinary skill would understand from the'504 Patent that the inventors were in possession of the claimed formulation comprising, among other features, pure solid state alkaline salts of (–)-omeprazole. (Davis Decl. ¶ 95; AZ SOF ¶¶ 130–132.) The '504 Patent describes throughout its specification that the alkaline salts products of (–)-omeprazole are "crystalline." (*See, e.g.*, Parezo Decl. Exh. B, col.1 ll.56–58; col.3 ll.35–37, 40–41.) Multiple examples set forth in the '504 Patent—Examples 2, 5 and 6—detail the preparation of alkaline salts of (–)-omeprazole in crystalline form and as powder. For example, Example 6 states that "[t]he product was crystalline as shown by powder X-ray diffraction . . . ." (*Id.* col.8 ll.49–50.) The plain meaning of "solid state" includes solid material such as the crystals and powder expressly described in the '504 Patent specification. (Davies Decl. ¶¶ 83; 95; 120–22; AZ SOF ¶¶ 117–129.)

Finally, the phrase "solid state" was endorsed by the Examiner in the Interview Summary. (Goffney Decl. ¶ 38; *see* Defs.' Rathinam Decl. Exh. 3, HAN0039582; AZ SOF ¶ 98.) The Examiner is required to address a claim term by using their "plain meaning," which is the meaning given to the term by those of ordinary skill in the art. (Goffney Decl. ¶ 37 (citing MPEP § 2111.01, 2100-44 to -45 (6th ed. rev. 2, July 1996)); AZ SOF ¶ 100.) Also, the USPTO directs examiners to consider all Section 112 issues, including written description, during examination. (Goffney Decl. ¶ 39; AZ SOF ¶ 101.) Accordingly, the Examiner considered whether the agreed-upon claim term "solid state" was in compliance with the written description requirement. (Goffney Decl. ¶ 40; AZ SOF ¶ 104.) Further, the Examiner is charged with ensuring that claim language has sufficient written description, again by applying the understanding of those of ordinary skill in the art. MPEP at § 2163.04, 2100-131 to -132. In particular, the Examiner is charged with analyzing new claim language to ensure that no new

matter is presented in claim amendments. *See id.* at §§ 2163.05, 2163.06, 2100-132 to -134. Thus, the fact that *the Examiner* endorsed the term "solid state" evidences that the term has a plain meaning to persons of ordinary skill in the art and demonstrates that the USPTO specifically considered whether there was adequate written description for the term, and concluded that there was.

D. A person of ordinary skill in the art could make and use "pure solid state alkaline salts"

Enablement is generally a fact-dependent inquiry, and in this case there are numerous material facts in dispute. The specification of the '504 Patent properly and adequately enables a person of ordinary skill in the art to make and use the pharmaceutical formulations and methods of claims 1, 2, 4, 6 and 7 through working examples, and the amount of direction and guidance it provides. The facts that led to allowance of claims 1, 2, 4, 6 and 7 also support a conclusion that the USPTO considered and determined that pure "solid state" alkaline salts were enabled by the '504 patent.

1. The facts relevant to evaluation of the In re Wands factors are in dispute

a. The breadth of the claims is in dispute

The scope of claims 1, 2, 4, 6 and 7 is disputed. Hanmi's Dr. Genck concludes that the claim scope is allegedly undefined, because the term "solid state" is allegedly undefined. (Genck Decl.[6] ¶ 62; Defs.' Br. Summ. J. 19.) Dr. Genck's opinion and conclusion is based on an instruction, presumably from Hanmi's counsel, to exclude "solid forms" from the plain and

[6] References to "Genck Decl." herein refer to "Declaration of Wayne J. Genck, Ph.D." filed by Hanmi as D.I. 108 with Motion 3.

ordinary meaning of the claim phrase "solid state."[7] (*Id.*) Professor Davies disagrees and explains that one of ordinary skill in the art would have understood the plain and ordinary meaning of "solid state" to be *solid material* in any form. (Davies Decl. ¶¶ 83; 136; AZ SOF ¶¶ 109–134.) Solid material would have included at least crystalline solids, amorphous solids and powders, which are disclosed in at least the Examples of the '504 Patent. (Davies Decl. ¶¶ 83; 136; AZ SOF ¶¶ 117–119; 134.)

Because all justifiable inferences are to be drawn in favor of the non-moving party, the Court must assume that the facts and views presented by Professor Davies are correct, and that the term "solid state" is clear and well-defined to a person of ordinary skill.

b. The amount of direction and guidance is in dispute

Hanmi argues that "solid state" is not disclosed and that the specification provides no direction or guidance for making a "solid state" salt. (Defs.' Br. Summ. J. 20 (citing internal Section [II]-B-1 on written description).) Professor Davies, however, explains that the '504 Patent provides full direction and guidance on how to prepare and identify alkaline salts of esomeprazole in the solid state. (Davies Decl. ¶¶ 137–38; AZ SOF ¶ 135.) The '504 Patent describes crystalline alkaline salts of esomeprazole that are obtained using the methods of preparation disclosed in the specification. (*See, e.g.*, Parezo Decl. Exh. B, col.3 ll.40–41; col.4 ll.58–61; AZ SOF ¶ 136.) Professor Davies also explains that it would have been clear to a

[7] "I am informed that the Court considered the meaning of the term 'solid state' in prior litigation involving the '504 patent. Based on that record, I have been asked to assume that the term 'solid state' in the '504 patent is to be ascribed its plain and ordinary meaning to one of ordinary skill in the art at in 1993-1995, ***but I am informed that the term does not mean a 'solid form' or 'a solid form rather than a liquid, such as, a syrup or oil.'***" (Genck Declaration ¶ 35 (emphasis added).)

person of ordinary skill in the art that the crystalline alkaline salts of esomeprazole are in a "solid state" because crystalline material is solid material. (Davies Decl. ¶ 137; AZ SOF ¶ 137.)

c. The presence of working examples is in dispute

Hanmi takes the bizarre position that the examples of the '504 Patent do not describe how to make and use a "solid state" alkaline salt of (–)-omeprazole. (Defs.' Br. Summ. J. 20 (citing internal Section [II]-B-1 on written description).) Professor Davies disagrees and explains that the examples in the '504 Patent provide detailed procedures for preparing alkaline salts of (–)-omeprazole in the solid state. (AZ SOF ¶ 130.) For example, Examples 2, 5 and 6 detail procedures that prepare salts of (–)-omeprazole as powders and crystalline forms. Both forms are solid materials and are thus "solid state". (Davies Decl. ¶¶ 139–47; AZ SOF ¶¶ 141–144.) Example 6, in particular, describes how to prepare a magnesium salt of (–)-omeprazole and states that "[t]he product was crystalline as shown by powder X-ray diffraction . . . ." (Davies Decl. ¶ 139 (citing Parezo Decl. Exh. B, col.8 ll.49–50); AZ SOF ¶ 143.) Thus, the procedures detailed in at least Examples 2, 5 and 6 of the '504 Patent specification teach a person of ordinary skill to how to make and use solid state alkaline salts of (–)-omeprazole. (Davies Decl. ¶¶ 139–47; AZ SOF ¶ 144.)

d. The quantity of experimentation is in dispute

Professor Genck contends that "the amount of experimentation needed to develop 'solid state' alkaline salts of (–)-omeprazole at the time of the effective filing date in 1995 would have been impossible to quantify."[8] (Defs.' Br. Summ. J. 20.) This conclusion, appears to be based

[8] Hanmi states, without providing any evidence to satisfy its evidentiary burden for proving, that the effective filing date of the '504 Patent was in 1995. Hanmi's position on the effective filing date is incorrect. The effective filing date of the '504 Patent is 1993, as all claims in the '504 Patent are supported under ¶ 112 by the disclosure of SE 9301830, the foreign patent (continued…)

on his assumption that "solid state" cannot mean "solid form." Professor Davies explains that a skilled person, at the priority date of the '504 Patent, would have required at most a routine amount of experimentation, in light of the significant amount of direction and guidance provided by the '504 Patent specification, for obtaining the claimed solid state alkaline salts of esomeprazole. (Davies Decl. ¶ 148; AZ SOF ¶ 152.)

e. Professor Davies establishes that the *Wands* factors, when considered together, demonstrate at most routine experimentation would be required to make and use the claimed invention

Professor Davies concludes, based on his consideration of factors bearing on whether the amount of experimentation is "undue," that a person of ordinary skill in the art would have understood, based on the '504 Patent specification, how to make and use solid state alkaline salts of (–)-omeprazole, as recited in claims 1, 2, 4, 6 and 7, without undue experimentation. (Davies Decl. ¶ 148; AZ SOF ¶ 152.) In light of his opinions, there is at least a dispute of material fact precluding summary judgment.

Hanmi points to the decision in *Automotive Technologies International, Inc. v. BMW of North America, Inc.*, 501 F.3d 1274 (Fed. Cir. 2007) as purportedly "squarely on point." (Defs.' Br. Summ. J. 15.) Hanmi states that "the patent specification in *Automotive Technologies* at least provided a general overview of the nonenabled embodiment. Here, in contrast, the '504 Patent specification provides no disclosure of any kind . . . regarding how to make any 'solid state' alkaline salt of (–)-omeprazole." (Defs.' Br. Summ. J. 16.) *Automotive Technologies* is inapposite to the present case, because the '504 Patent specification does in fact provide ample

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document to which the '504 Patent claims priority. SE 9301830 was filed on May 28, 1993, and therefore the '504 Patent is entitled to this 1993 date as its effective filing date.

disclosure, including detailed procedures for preparing the claimed alkaline salts of (–)-omeprazole in solid state.

2. The Prosecution History of the ’504 Patent Further Shows That the Enablement Requirement Is Met

The prosecution history of the ’504 Patent also demonstrates that the USPTO considered whether pure “solid state” alkaline salts were enabled and concluded that it was. As noted above, the phrase “solid state” was endorsed by the Examiner herself in the Interview Summary. (Goffney Decl. ¶ 38; *see* Defs.’ Rathinam Decl. Exh. 3, HAN0039582; AZ SOF ¶ 98.) The Examiner is charged with ensuring that claim language is enabled by the specification. (Goffney Decl. ¶ 39; AZ SOF ¶ 190.) Accordingly, the Examiner had considered whether the endorsed term “solid state” was in compliance with the enablement requirement. (Goffney Decl. ¶ 40.) The fact that the Examiner herself agreed to the term “solid state” shows that the USPTO has determined that one of skill in the art would understand how to make and use alkaline salts of (–)-omeprazole without undue experimentation based on the teachings of the ’504 Patent specification. Therefore, the endorsement of the term by the Examiner shows that the USPTO considered that “solid state” was enabled by the ’504 Patent specification.

Hanmi’s enablement argument mischaracterizes the prosecution history of the ’504 Patent. (*See* Defs.’ Br. Summ. J. 14.) Hanmi speculates that “solid state” was added to the claims to overcome a novelty rejection, based on the disclosure of an amorphous solid. The prosecution history shows only that the amorphous nature of the reference was not even at issue. (Davies Decl. ¶ 123–28.)

V. CONCLUSION

For the foregoing reasons, AstraZeneca respectfully requests that the Court deny Hanmi’s summary judgment Motion 3.

Respectfully submitted,

Dated: December 2, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2011, I caused a copy of the foregoing ASTRAZENECA'S BRIEF IN OPPOSITION TO HANMI'S MOTION FOR SUMMARY JUDGMENT NO. 3: INVALIDITY OF U.S. PATENT NO. 5,714,504 - CLAIMS 1-2, 4, 6 AND 7 BASED ON "SOLID STATE" and supporting documents to be served upon the following counsel by operation of the Court's electronic filing system and/or electronic mail:

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